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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/799,038	03/11/2004	Paul T. Gardiner	03490.000008.	6719
5514 7590 07/07/2009 FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112			EXAMINER CHOI, FRANK I	
			ART UNIT 1616	PAPER NUMBER
			MAIL DATE 07/07/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/799,038	<b>Applicant(s)</b> GARDINER ET AL.	
	<b>Examiner</b> FRANK I. CHOI	<b>Art Unit</b> 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 April 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 98,102-105 and 108-119 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 98,102-105 and 108-119 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 98, 102-105, 108-119 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabor (US Pat. 6,482,448) in view of Hastings et al. (US 2001/0041187), Miller et al. (US Pat. 6,019,999), Ostlund et al. (US Pat. 5,550,166), Shimizu et al. (US Pat. 6,004,926), Goldberg et al., and Goldberg.

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder, liquid form or bar form (Colum 6, lines 15-46, column 8, lines 30-33).

Hastings et al. discloses a performance-enhancing supplement in powder form which can be mixed with juice, water, milk or any other drinkable non-alcoholic beverage with the recommended daily serving being about 26 grams to about 78 grams in which the major ingredient is soy protein (Paragraphs 0006, 0007). It is disclosed that the supplement contains an amino acid premix of l-leucine, l-glutamine, l-alanine, glycine, l-arginine, l-lysine and that glutamine promotes anabolic conditions in muscle cells, increase rate of protein and glycogen synthesis, and indirectly promotes muscle growth, that alanine is an important source of energy for muscle tissue and that arginine is essential for optimal muscle growth and tissue repair (Paragraphs 0008-0010). It is disclosed that the supplement contains fat in the form of medium

Art Unit: 1616

chain triglycerides with improve the absorption of the amino acids (Paragraph 0012) It is disclosed that the dietary supplement should include carbohydrate which supplies an energy source (paragraph 0014). It is disclosed that L-carnitine is added as it has been shown that athletes who supplement their diet with the same convert fat to energy more efficiently (Paragraph 0017). It is disclosed that creatine is included in the dietary supplement to shorten the time necessary for the body to generate replacement creatine phosphate and significantly reduce muscle recovery time between short duration, high intensity activities (Paragraph 0016). It is disclosed that individuals on an intense physical training regiment will gain optimal results at the higher levels of consumption whereas those on moderate or casual workout regimens will require less (Paragraph 0006).

Miller et al. discloses that for resistance-trained athletes the intake for protein should be approximately twice the normal RDI and that a preferred source of animal protein is dairy whey (column 1, lines 60-68, Column 2, line 1). A liposomal, ion-exchange whey protein is disclosed which is effective in increasing lean body mass, muscle mass with appropriate exercise and improving exercise performance (column 7, lines 46-60).

Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity (Abstract). It is disclosed that inositol compounds improve insulin sensitivity (Columns 2, 3).

Shimizu et al. disclose a supplement containing protein, fat and carbohydrate which is ingested before, during and/or after exercise, particularly after the exercise immediately preceding a resting period, the protein is selectively taken up in the muscle tissue in the state where the process of protein assimilation is invigorated by the exercise, while the fat is

Art Unit: 1616

combused as an energy source and consumed, with the resulting improvement in body composition contributing neatly to shape-up, body building, muscle increase and augmentation of the dynamic strength of muscles (Column 1, lines 55-68, Column 2, lines 1-64).

Goldberg et al. disclose that an increase in muscle weight reflects an increase in protein and results from greater protein synthesis and reduced protein breakdown and that hypertrophy leads to greater maximal tension development (Abstract).

Goldberg disclose that insulin reduces overall protein breakdown in skeletal muscle (Abstract).

Tabor discloses a dietary supplement which comprises a soy formulation and preferably comprising 70-90%, by weight, protein, 1-5%, by weight fat, and 1-25%, carbohydrate which may in the form of a powder, liquid form or bar form .The difference between the prior art and the claimed invention is that the Tabort does not expressly disclose a method of supplementing the diet of an athlete or supplementing the diet of a human by administering a dietary supplement which mimics or enhances insulin activity to enhance muscle size and strength.

However, the prior art amply suggests the same as Tabor discloses amounts of protein and carbohydrate which encompass or overlap the claimed amounts, Hastings discloses the incorporation of L-arginine, glutamine, carnitine, alanine, creatine, Miller discloses that whey proteins are effective in increasing lean body mass, muscle mass, Ostlund et al. disclose that pinitol and derivatives and metabolites thereof are useful in nutritional composition for treating conditions associated insulin resistance including complications arising from athletic activity, Ostland and Hastings discloses that compositions can be in the form of powders which can be mixed with a diluent such as water and Shimizu discloses that supplements can be administered to athletes or immediately after exercise. Further, the Goldberg references discloses that muscle

Art Unit: 1616

hypertrophy can lead to greater maximal tension development and that muscle size is a reflection of increased protein synthesis and decreased protein breakdown and that insulin reduces overall protein breakdown in skeletal muscle tissue. As such, it would have been well within the skill of and one of ordinary skill in the art would have been motivated to modify the prior art as above with the expectation that the use of said composition would increase muscle mass and strength.

The examiner has duly considered the Applicant's arguments but deems them unpersuasive for the reasons of record and the further reasons below.

The Supreme Court in *KSR International Co. v. Teleflex Inc.*, held the following:

(1) the obviousness analysis need not seek out precise teachings directed to the subject matter of the challenged claim and can take into account the inferences and creative steps that one of ordinary skill in the art would employ;

(2) the obviousness analysis cannot be confined by a formalistic conception of the words teaching, suggestion and motivation, or by overemphasis on the importance of published articles and the explicit content of issued patents;

(3) it is error to look only the problem the patentee was trying to solve-any need or problem known in the field of endeavor at the time of invention and addressed by the prior art can provide a reason for combining the elements in the manner claimed;

(4) it is error to assume that one of ordinary skill in the art in attempting to solve a problem will be led only to those elements of prior art designed to solve the same problem-common sense teaches that familiar items may have obvious uses beyond their primary purposes, and in many cases one of ordinary skill in the art will be able to fit the teachings of multiple patents together like pieces of a puzzle (one of ordinary skill in the art is not automaton);

(5) it is error to assume that a patent claim cannot be proved obvious merely by showing that the combination of elements was “obvious to try”. *KSR International Co. v. Teleflex Inc.*, 82 USPQ2d 1385, 1396, 1397 (U.S. 2007).

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

In this case, the Applicant's argument appears to be directed to the specific references and to what they disclose and do not disclose. However, in view of KSR and the other court opinions cited above, there is no requirement that each reference specifically disclose each element of the claimed invention individually. As such, the mere fact that an individual reference does not disclose one or more elements of the claimed invention is not sufficient to overcome the claimed rejection. Furthermore, KSR indicates that one of ordinary skill in the art is able to fit the teachings of multiple patents together like pieces of a puzzle and have different reasons for combining the prior art which are different from the Applicants reasons for arriving at the claimed invention. The Examiner has provided the disclosure and reasoning for doing the same above.

Art Unit: 1616

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Wednesday and Thursday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi  
Patent Examiner  
Technology Center 1600  
July 7, 2009

/John Pak/  
Primary Examiner, Art Unit 1616